Remarks

In the final Office action of March 7, 2003, Paper No. 17, claims 1-21 are pending and were rejected. The drawings filed on June 16, 2000, and December 16, 2002, were accepted by the Examiner. However, the drawings filed on June 16, 2000, were objected to by the Draftsperson. Acknowledgment was made of a claim for foreign priority under 35 U.S.C. 119(a)-(d) or (f). All of the certified copies of the priority documents were received by the Patent Office. Acknowledgment was also made of a claim for domestic priority under 35 U.S.C. 120 and/or 121. Claims 17-19 were rejected under 35 U.S.C. 102(b) as being anticipated by Lazarus, and claims 17 and 18 were rejected under 35 U.S.C. 102(b) as being anticipated by Partika. Claims 1-16, 20 and 21 were rejected under 35 U.S.C. 103(a) as being unpatentable over Folkman in view of Shanley, MacLeod, Smith, Arlers, Racz, Jiang, Singer, Draenert, Haynie, Hertzmann, and Baker. In response to applicant's arguments filed on December 16, 2002, the Examiner found them not to be persuasive. In response to applicant's anticipation argument, the Examiner indicated that the claims need only "read on" something in the reference. Furthermore, the Examiner indicated that the manner in which a device is intended to be employed does not differentiate prior art apparatus satisfying the claimed structural limitations. The Examiner also responded with an intended use argument with respect to the 103 rejection of claims 1-16, 20 and 21.

In response to the Draftsperson's objections to the drawings, a set of new drawings overcoming the Draftsperson's objections is being sent to the Patent Office under separate cover. A copy of the new drawings is enclosed for the Examiner.

By this amendment, independent claims 1, 17, 20 and 21 are being amended to positively recite that the invention is directed to either a tray of vertebroplasty components or a vertebroplasty kit for use in performing

vertebroplasty. In particular, the tray of vertebroplasty components comprises a local anaesthesia assembly, a surgical cutting instrument, a device for injection of a hardenable liquid biomaterial into a vertebral body and now more specifically, a bone cement assembly for preparation of the hardenable liquid biomaterial for strengthening the vertebral body.

More specifically with respect to the anticipation rejection, independent claim 17 is now directed to "a vertebroplasty" kit comprising a first tray of "vertebroplasty injection" components and a second tray of "vertebroplasty injection" components such that the second tray of vertebroplasty injection components can remain sterile for use in another vertebral body if the first vertebroplasty injection sufficiently strengthens the vertebral body. As a result of this amendment, claims 17, as amended herein, 18 and 19 positively recite a "vertebroplasty" kit comprising first and second trays of "vertebroplasty injection" components.

Lazarus is directed to peritoneal fluid treatment apparatus, package and method, whereas Partika is directed to a skin preparation tray for use in surgical procedures. As previously presented, Lazarus is directed to a peritoneal fluid treatment and not vertebroplasty, which is now positively recited in independent claim 17, as amended herein, by first and second trays of vertebroplasty injection components. A peritoneal fluid treatment is directed to fluid in the peritoneal cavity and has nothing to do with a vertebral body. As also previously presented, Partika, like Lazarus, includes a tray for skin preparation and a separate tray for performing a given medical procedure. However, there are no vertebroplasty injection components disclosed in either of the two references for claims 17-19 to "read on." In view thereof, applicant submits that the vertebroplasty kit as claimed in independent claim, as amended herein, and dependent claims 18 and 19 are not identically disclosed by Lazarus or Partika, and it is requested that the rejection of these claims under 35 U.S.C. 102(b) as being anticipated by Lazarus or Partika, be withdrawn. With respect to the rejection of claims 1-16, 20 and 21

under 35 U.S.C. 103(a) as being unpatentable over Folkman in view of Shanley, etc., applicant again submits that none of the cited references are directed to performing a vertebroplasty medical procedure and, in particular, a tray of vertebroplasty components and, more particularly, a bone cement assembly for the preparation of the hardenable liquid biomaterial for strengthening the vertebral body. In claim 20 as amended herein, the tray of vertebroplasty components includes a liquid monomer, a polymer powder, and an opacifier. In addition, independent claims 20 and 21, as amended herein, require a vertebroplasty needle. In view of the now positive recitation of vertebroplasty components, and more specifically a bone cement assembly for preparing a hardenable liquid biomaterial for strengthening a vertebral body and a vertebral body injection device, applicant again submits that none of the cited references are directed to performing a vertebroplasty medical procedure including vertebroplasty components and, in particular, a bone cement assembly in preparation of a hardenable liquid biomaterial for strengthening the vertebral body. Using unpermitted hindsight, the Examiner has simply taken applicant's claimed kit of vertebroplasty components and utilized the listed elements as a grocery list in finding the individual elements of applicants claims in a series of unrelated references.

The Jiang reference is directed to a biodegradable bone cement. This biodegradable bone cement is directed in repairing hard tissue such as bone or for bonding prosthetics to hard tissue. There is absolutely no teaching or suggestion for performing a vertebroplasty procedure or listing a tray of vertebroplasty components for performing such a procedure. Further, teaching away from the cited references, applicant's bone cement is for strengthening a vertebral body rather than allowing it to biodegrade.

The Baker reference is directed to a polymethylmethacrylate bone cement for securing metal and plastic prosthesis to bone and to the methods of preparing such bone cement. Again, this reference does not teach or suggest a

tray of vertebroplasty components and, in particular, a bone cement for injecting into a vertebral body to strengthen it.

Applicants again submit that there is no motivation in the cited references to form a tray of vertebroplasty components as claimed in applicant's invention. Lacking such motivation in any of the references, the Examiner has stated that a surgeon or any medical practitioner can meet applicant's claimed invention by simply purchasing the components of the cited references, but where did the practitioner get the grocery list? Even doing so, simply purchasing the components of the cited references is not going to result in a tray of vertebroplasty components such as a bone cement assembly for preparation of a hardenable liquid biomaterial for strengthening a vertebral body and a device for injection such as a vertebroplasty needle for injection of the biomaterial into the vertebral body. None of the cited references even mention a vertebroplasty procedure or how to arrange a tray of vertebroplasty components to perform such medical procedure. Furthermore, the Examiner indicates that the rationale to modify or combine the prior art does not have to be expressly stated in the prior art. The Examiner further contends that the rationale to modify can be impliedly contained in the prior art or may be reasoned from knowledge generally available to one ordinarily skilled in the art. Applicant is a board certified interventional radiologist and not a surgeon or just any medical practitioner. Through his experience and insight, applicant conceived of this tray of vertebroplasty components for use in performing a vertebroplasty medical procedure. The bone cement is subject to time constraints due to the heating and setting of the bone cement. Arranging a tray of these vertebroplasty components to allow the physician to readily prepare and inject a hardenable liquid into a vertebral body under these time constraints as well as assuring that the treatment has been effective is more than common knowledge generally available to any medical practitioner as suggested by the Examiner. Thus, the Examiner is invited to provide a reference or publication supporting his contention that such common

knowledge is generally available to any medical practitioner for performing a vertebroplasty procedure. In the absence thereof, applicant submits that the Examiner has failed to present a prima facie case of obviousness and that the cited references do not teach or even suggest applicant's claimed tray of vertebroplasty components. In view thereof, applicants request that the rejection of claims 1, 6-16, 20 and 21, as amended herein, under 35 U.S.C. as being unpatentable over Folkman in view of Shanley, etc., be withdrawn.

The reexamination and reconsideration of this application is respectfully requested, and it is further requested that the application be passed to issue.

Although the foregoing discussion is believed to be dispositive of the issues in this case, applicants' attorney requests a telephone interview with the Examiner to discuss any unresolved issues remaining after the Examiner's consideration of this amendment and response.

Respectfully submitted,

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Enclosures:
Copy of new drawings to Office Draftsperson